PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing (*day/month/year*)	03 NOV 2005
Applicant's or agent's file reference 2997-74-PCT	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date (*day/month/year*)	Priority date (*day/month/year*)
PCT/US05/02177	19 January 2005 (19.01.2005)	19 January 2004 (19.01.2004)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61K 31/20 and US Cl.: 514/558

Applicant

MARTEK BIOSCIENCES CORPORATION

1. This opinion contains indications relating to the following items:

- [X] Box No. I — Basis of the opinion
- [ ] Box No. II — Priority
- [ ] Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV — Lack of unity of invention
- [X] Box No. V — Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI — Certain documents cited
- [ ] Box No. VII — Certain defects in the international application
- [ ] Box No. VIII — Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(*b*) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	22 September 2005 (22.09.2005)	Sreenivasan Padmanabhan Telephone No. 703-308-1235

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/02177

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

☒ the international application in the language in which it was filed

☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ on paper

☐ in electronic form

c. time of filing/furnishing

☐ contained in the international application as filed.

☐ filed together with the international application in electronic form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/02177

Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-123	YES
	Claims NONE	NO
Inventive step (IS)	Claims NONE	YES
	Claims 1-123	NO
Industrial applicability (IA)	Claims 1-123	YES
	Claims NONE	NO

2. Citations and explanations:

Claims 1-123 meet the criteria set out in PCT Article 33(2), because the prior art does not teach or fairly suggest a claimed method comprising mechanism of the deficiency or dysfunctions of Reelin deficiency.
Claims 1-123 lack an inventive step under PCT Article 33(3) as being obvious over HORROBIN (U.S.Patent No. 5,516,800) in view of BRADLEY et al. (U.S.Patent No. 6,197,764 B1).
HORROBIN teaches treatment of negative symptoms of schizophrenia can be treated with the combination comprising docosahexaenoic acid. (abstract)
BRADLEY et al. teach a composition comprising docosahexaenoic acid useful for the treatment of psychological disorders such as schizophrenia.
Neither reference teaches the mechanism of action of effecting Reelin deficiency or dysfunction.
The mechanism of action of effecting Reelin deficiency or dysfunction is obvious because the mechanism by which the active ingredient gives the pharmacological effect does not alter the fact that the same compound has been previously used to obtain the same pharmacological effects which would result from the claimed method of treating schizophrenia. The patient, condition to be treated and the effect are the same. An explanation of why that effect occurs does not make novel or even unobvious the treatment of the conditions encompassed by the claims.
Claims 1-123 meet the criteria set out in PCT Article 33(4) since a method to treat a Reelin deficiency or dysfunction, comprising administering to a patient diagnosed with or suspected of having a Reelin deficiency or dysfunction an amount of a polyunsaturated fatty acid (PUDA) to compensate for the effects of Reelin deficiency or dysfunction in the patient has an industrial applicability in pharmaceutical art.